

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,  
AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION**

**THIS DOCUMENT RELATES TO:**

*Gaston Roberts et al. v. Zhejiang  
Huahai Pharmaceutical Co., et al.,*

Case No. 1:20-cv-00946-RBK-JS

MDL No. 2875

Honorable Renée Marie Bumb  
District Court Judge

**DECLARATION OF NINA ROSE IN SUPPORT OF DEFENDANTS' MOTION  
TO EXCLUDE THE OPINIONS OF DR. FAREEHA SIDDIQUI**

I, Nina Rose, declare as follows:

I am an attorney and a partner with the law firm Kirkland & Ellis LLP, counsel for Defendants Zhejiang Huahai Pharmaceutical Co., Ltd., Solco Healthcare U.S., LLC, and Princeton Pharmaceutical Inc. ("Defendants") in the above-captioned matter. The facts stated in this Declaration are true of my own personal knowledge. I submit this Declaration in Support of Defendants' Memorandum of Law in Support of Motion to Exclude the Opinions of Dr. Fareeha Siddiqui.

1. Attached hereto as **Exhibit 1** is a true and correct copy of the Expert Report of Fareeha Siddiqui, M.D., dated Mar. 10, 2025.
2. Attached hereto as **Exhibit 2** is a true and correct copy of Kazuo Tarao et al., *Real impact of liver cirrhosis on the development of hepatocellular*

*carcinoma in various liver diseases—meta-analytic assessment*, 8 *Cancer Med.* 1054 (2019).

3. Attached hereto as **Exhibit 3** is a true and correct copy of Rongtao Lai et al., *Incidence rates of hepatocellular carcinoma based on risk stratification in steatotic liver disease for precision medicine: A real-world longitudinal nationwide study*, *PLoS Med.* (2024).
4. Attached hereto as **Exhibit 4** is a true and correct copy of Deposition Transcript of Mark Lockhart, M.D., dated Feb. 13, 2025.
5. Attached hereto as **Exhibit 5** is a true and correct copy of medical record bates stamped GRobertsJr-UABHIM-MD-000082 through GRobertsJr-UABHIM-MD-000090.
6. Attached hereto as **Exhibit 6** is a true and correct copy of medical record bates stamped GRobertsJr-CA-000656 through GRobertsJr-CA-000663.
7. Attached hereto as **Exhibit 7** is a true and correct copy of Deposition Transcript of Fareeha Siddiqui, dated Apr. 29, 2025.
8. Attached hereto as **Exhibit 8** is a true and correct copy of Mary E. Rinella et al., *A multisociety Delphi consensus statement on new fatty liver disease nomenclature*, 79 *J. of Hepatology* 1542 (2023).
9. Attached hereto as **Exhibit 9** is a true and correct copy of the Expert Report of Nadim Mahmud, M.D., M.S., M.P.H., M.S.C.E.

10. Attached hereto as **Exhibit 10** is a true and correct copy of Jonathan G. Stine et al., *Systematic review with meta-analysis: risk of hepatocellular carcinoma in non-alcoholic steatohepatitis without cirrhosis compared to other liver diseases*, 48 Ailment Pharmacol Ther. 696 (2018).
11. Attached hereto as **Exhibit 11** is a true and correct copy of Fahim Ebrahimi, et al., *Familial coaggregation of MASLD with hepatocellular carcinoma and adverse liver outcomes: Nationwide multigenerational cohort study*, 79 J. of Hepatology 1374 (2023).
12. Attached hereto as **Exhibit 12** is a true and correct copy of medical record bates stamped GRobertsJr-CA-000729 through GRobertsJr-CA-000730.
13. Attached hereto as **Exhibit 13** is a true and correct copy of medical record bates stamped GRobertsJr-AMG-000043 through GRobertsJr-AMG-000047.
14. Attached hereto as **Exhibit 14** is a true and correct copy of Ping Wang et al., *Diabetes mellitus and risk of hepatocellular carcinoma: a systematic review and meta-analysis*, 28 Diabetes Metab. Res. Rev. 109 (2012).
15. Attached hereto as **Exhibit 15** is a true and correct copy of Xuancheng Xie et al., *Correlation analysis of metabolic characteristics and the risk of metabolic-associated fatty liver disease -related hepatocellular carcinoma*, Scientific Reports (2022).

16. Attached hereto as **Exhibit 16** is a true and correct copy of Catherine Mezzacappa et al., *HCC is associated with diabetes and longitudinal blood glucose control in a national cohort with cirrhosis*, Hepatology Commc'ns. (2023).
17. Attached hereto as **Exhibit 17** is a true and correct copy of a collection of medical records with bates stamp GRobertsJR-CA-000722; GRobertsJR-ESMS-000016-20; GRobertsJR-ESMS-000051-56; GRobertsJR-ESMS-000045-50; GRobertsJR-ESMS-00002-06; GRobertsJR-AMG-000032-35; GRobertsJR-AMG-000028-30; GRobertsJR-CA-000209-11.
18. Attached hereto as **Exhibit 18** is a true and correct copy of Deposition Transcript of Darryle Bullard, M.D., dated Feb. 13, 2025.
19. Attached hereto as **Exhibit 19** is a true and correct copy of Deposition Transcript of Donald B. Sanders, M.D., dated Oct. 8, 2021.
20. Attached hereto as **Exhibit 20** is a true and correct copy of Marc-Andre Cornier et al., *Assessing adiposity: a scientific statement from the American Heart Association*, 124 Circulation 1996, 1997 (2011).
21. Attached hereto as **Exhibit 21** is a true and correct copy of Baek Gyu Jun et al., *Impact of overweight and obesity on the risk of hepatocellular carcinoma: a prospective cohort study in 14.3 million Koreans*, 127 Brit. J. of Cancer 109 (2022).

22. Attached hereto as **Exhibit 22** is a true and correct copy of Yi Chen et al., *Excess body weight and the risk of primary liver cancer: An updated meta-analysis of prospective studies*, 48 Eur. J. of Cancer 2137 (2012).
23. Attached hereto as **Exhibit 23** is a true and correct copy of medical record bates stamped GRobertsJr-UABHIM-MD-000001 through GRobertsJr-UABHIM-MD-000010.
24. Attached hereto as **Exhibit 24** is a true and correct copy of medical record bates stamped GRobertsJr-PPR-000106.
25. Attached hereto as **Exhibit 25** is a true and correct copy of medical record bates stamped GRobertsJr-SouCC-000235 through GRobertsJr-SouCC-000238.
26. Attached hereto as **Exhibit 26** is a true and correct copy of medical record bates stamped GRobertsJr-UABHIM-MD-000082 through GRobertsJr-UABHIM-MD-000090.
27. Attached hereto as **Exhibit 27** is a true and correct copy of medical record bates stamped GRobertsJr-SouCC-000250 through GRobertsJr-SouCC-000251.
28. Attached hereto as **Exhibit 28** is a true and correct copy of medical record bates stamped GRobertsJr-UABHIM-MD-000029 through GRobertsJr-UABHIM-MD-000037.

29. Attached hereto as **Exhibit 29** is a true and correct copy of medical record bates stamped GRobertsJr-PPR-000093 through GRobertsJr-PPR-000097.
30. Attached hereto as **Exhibit 30** is a true and correct copy of Willy Gomm et al., *N-Nitrosodimethylamine-Contaminated Valsartan and the Risk of Cancer*, 118 Deutsches Arzteblatt Int'l 357, 360 (2021).
31. Attached hereto as **Exhibit 31** is a true and correct copy of Imene Mansouri et al., *N-Nitrosodimethylamine-Contaminated Valsartan and the Risk of Cancer: A Nationwide Study of 1.4 Million Valsartan Users*, 11 J. of the Am. Heart Assoc. (2022).
32. Attached hereto as **Exhibit 32** is a true and correct copy of Piyush Nathani et al., *Hepatocellular carcinoma tumour volume doubling time: a systematic review and meta-analysis*, 70 Gut 401 (2021).
33. Attached hereto as **Exhibit 33** is a true and correct copy of Evelyn Calderon-Martinez et al., *Prognostic Scores and Survival Rates by Etiology of Hepatocellular Carcinoma: A Review*, 15 J. Clin. Med. Res. 200, 2023 (2023).
34. Attached hereto as **Exhibit 34** is a true and correct copy of Sangheun Lee et al., *Subclassification of Barcelona Clinic Liver Cancer B and C hepatocellular carcinoma: a cohort study of the multicenter registry database*, 31 J. of Gastroenterology & Hepatology 842 (2016).

35. Attached hereto as **Exhibit 35** is a true and correct copy of Richard Peto et al., *Dose and time relationships for tumor induction in the liver and esophagus of 4,080 inbred rats by chronic ingestion of N-nitrosodiethylamine or N-nitrosodimethylamine*, 51 *Cancer Research* 6452 (1991).
36. Attached hereto as **Exhibit 36** is a true and correct copy of Giovanna Fattovich et al., *Hepatocellular carcinoma in cirrhosis: incidence and risk factors*, 127 *Gastroenterology* 35, 36 (2004).
37. Attached hereto as **Exhibit 37** is a true and correct copy of Deposition Transcript of Samuel Hooks, dated Jan. 29, 2025.
38. Attached hereto as **Exhibit 38** is a true and correct copy of Deposition Transcript of William Sawyer, dated May 1, 2025.
39. Attached hereto as **Exhibit 39** is a true and correct copy of the Expert Report of Christopher Mele.
40. Attached hereto as **Exhibit 40** is a true and correct copy of Deposition Transcript of Christopher Mele, dated May 8, 2025.
41. Attached hereto as **Exhibit 41** is a true and correct copy of Dina Mansour & Stuart McPherson, *Management of decompensated cirrhosis*, 18 *Clinical Medicine* 60 (2018).
42. Attached hereto as **Exhibit 42** is a true and correct copy of Amit G. Singal et

- al., *AASLD Practice Guidance on prevention, diagnosis, and treatment of hepatocellular carcinoma*, 78 *Hepatology* 1922 (2023).
43. Attached hereto as **Exhibit 43** is a true and correct copy of *EASL [European Association for the Study of the Liver] Clinical Practice Guidelines on the management of hepatocellular carcinoma*, 82 *J. of Hepatology* 315 (2025).
44. Attached hereto as **Exhibit 44** is a true and correct copy of Yuri Cho et al., *Overview of Asian clinical practice guidelines for the management of hepatocellular carcinoma: An Asian perspective comparison*, 29 *Clinical & Molecular Hepatology* 252 (2023).
45. Attached hereto as **Exhibit 45** is a true and correct copy of Bonnie Bengtsson et al., *The risk of hepatocellular carcinoma in cirrhosis differs by etiology, age and sex: A Swedish nationwide population-based cohort study*, 10 *United European Gastroenterology J.* 465 (2022).
46. Attached hereto as **Exhibit 46** is a true and correct copy of Juan Vaz et al., *Unrecognized liver cirrhosis is common and associated with worse survival in hepatocellular carcinoma: A nationwide cohort study of 3473 patients*, 293 *J. of Internal Med.* 184 (2022).
47. Attached hereto as **Exhibit 47** is a true and correct copy of Stuart McPherson et al., *Simple non-invasive fibrosis scoring systems can reliably exclude advanced fibrosis in patients with non-alcoholic fatty liver disease*,



- 59 Gut 1265 (2010).
48. Attached hereto as **Exhibit 48** is a true and correct copy of Mohammad Shabab Siddiqui et al., *Diagnostic Accuracy of Noninvasive Fibrosis Models to Detect Change in Fibrosis Stage*, 17 Clinical Gastroenterology Hepatology 1877 (2019).
49. Attached hereto as **Exhibit 49** is a true and correct copy of Fasiha Kanwal et al., *Metabolic dysfunction—associated steatotic liver disease: Update and impact of new nomenclature on the American Association for the Study of Liver Diseases practice guidance on nonalcoholic fatty liver disease*, 79 Hepatology 1212 (2023).
50. Attached hereto as **Exhibit 50** is a true and correct copy of Philip J. Johnson et. al, *Progression of chronic liver disease to Hepatocellular (Liver) carcinoma: implications for surveillance and management*, BJC Reps. (2024).
51. Attached hereto as **Exhibit 51** is a true and correct copy of medical record bates stamped GRobertsJr-TH-MD-000938 through GRobertsJr-TH-MD-000955.
52. Attached hereto as **Exhibit 52** is a true and correct copy of Rohit Loomba et al., *AGA clinical practice update on screening and surveillance for hepatocellular carcinoma in patients with nonalcoholic fatty liver disease:*

*expert review*, 158 *Gastroenterology* 1822 (2020).

53. Attached hereto as **Exhibit 53** is a true and correct copy of Alessandro Mantovani & Giovanni Targher, *Type 2 diabetes mellitus and risk of hepatocellular carcinoma: spotlight on nonalcoholic fatty liver disease*. 5 *Ann. Transl. Med.* (2017).
54. Attached hereto as **Exhibit 54** is a true and correct copy of Carlo La Vecchia et al., *Diabetes mellitus and the risk of primary liver cancer*. 73 *Int. J. Cancer* 204, 205 (1997).
55. Attached hereto as **Exhibit 55** is a true and correct copy of Wan-Shui Yang et al., *The Role of Pre-Existing Diabetes Mellitus on Hepatocellular Carcinoma Occurrence and Prognosis: A Meta-Analysis of Prospective Cohort Studies*, 6 *PLoS One* (2011).
56. Attached hereto as **Exhibit 56** is a true and correct copy of Beicheng Sun & Michael Karin, *Obesity, inflammation, and liver cancer*, 56 *J. of Hepatology* 704 (2012).
57. Attached hereto as **Exhibit 57** is a true and correct copy of W-P Koh et al., *Diabetes mellitus and risk of hepatocellular carcinoma: findings from the Singapore Chinese Health Study*, 108 *British J. of Cancer* 1182 (2013).
58. Attached hereto as **Exhibit 58** is a true and correct copy of S. Schlesinger et al., *Diabetes mellitus, insulin treatment, diabetes duration, and risk of*

*biliary tract cancer and hepatocellular carcinoma in a European court*, 24  
Annals of Oncology 2449 (2013).

59. Attached hereto as **Exhibit 59** is a true and correct copy of Qingyan Kong et al., *Impact of Metabolic Dysfunction-Associated Fatty/Steatotic Liver Disease on Hepatocellular Carcinoma Incidence and Long-Term Prognosis Post-Liver Resection: A Systematic Review and Meta-Analysis*, Academic Radiology (2025).

I certify under penalty of perjury that the foregoing is true and correct.

Dated: May 22, 2025

Respectfully submitted,

/s/ Nina R. Rose

Nina R. Rose (*pro hac vice*)  
**KIRKLAND & ELLIS LLP**  
1301 Pennsylvania Avenue  
Washington, D.C. 20004  
Tel: (202) 389-3394  
Fax: (202) 389-5200  
nina.rose@kirkland.com

*Attorney for Defendants Zhejiang  
Huahai Pharmaceutical Co., Ltd., Solco  
Healthcare U.S., LLC, and Princeton  
Pharmaceutical Inc.*

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on May 22, 2025, a true and correct copy of the foregoing document was served upon counsel of record via operation of the Court's electronic filing system.

Dated: May 22, 2025

Respectfully submitted,

*/s/ Nina R. Rose*

---

Nina R. Rose (*pro hac vice*)  
**KIRKLAND & ELLIS LLP**  
1301 Pennsylvania Avenue  
Washington, D.C. 20004  
Tel: (202) 389-3394  
Fax: (202) 389-5200  
nina.rose@kirkland.com

*Attorney for Defendants Zhejiang  
Huahai Pharmaceutical Co., Ltd., Solco  
Healthcare U.S., LLC, and Princeton  
Pharmaceutical Inc.*